## **EXHIBIT H**

# **EXHIBIT A**

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	Pro Hac to Be Submitted					
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12	IN SUPERIOR COURT FOR					
13	IN AND FOR THE COU	NTY OF MARICOPA				
14	BEATRICE MILLS,	) Case No. CV2011-000415				
15	Plaintiff,	}				
16	v.	DI A INTERESS EIDST				
17	BRISTOL-MYERS SQUIBB COMPANY,	) PLAINTIFF'S FIRST AMENDED COMPLAINT				
	SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and	}				
18	SANOFI-SYNTHEĽABO, INC.	(Assigned to the Honorable Sam Myers)				
19	Defendants.	}				
20		}				
21		·				
22						
23	COMES NOW Beatrice Mills, hereinafter referred to as the "Plaintiff" who files					
24	this Complaint, complaining of and for her c	ause of action against, BRISTOL-MYERS				
25	SQUIBB COMPANY, SANOFI-AVENTIS,	, U.S., L.L.C., SANOFI-AVENTIS, U.S.,				
26	INC., AND SANOFI-SYNTHELABO, INC	C., the Plaintiffs, by and through their				
27	undersigned attorney, for their Complaint against Defendants, state and allege as follows:					
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This action is brought by Plaintiff seeking damages for personal injuries and economic damages suffered as a result of a defective and dangerous pharmaceutical product, PLAVIX. Plaintiff's damages arose as a result of her ingestion of Defendants PLAVIX drug which was manufactured, marketed, distributed and sold by Defendants and/or Defendants representatives and placed in the stream of commerce in this state by Defendants.

I.

## **PARTIES**

## **PLAINTIFFS**

1. Plaintiff, Beatrice Mills, a natural person, is a citizen and resident of Fountain Hills, Maricopa County. Currently, Beatrice Mills resides at 16003 Burro Drive, Fountain Hills, Maricopa County, Arizona 85268, and was treated in said county for her injuries. At all times relative to this complaint, Beatrice Mills, resided at 739 Las Colinas, Chandler, Maricopa County, Arizona, 85249.

## **DEFENDANTS**

- 2. Defendant, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to manufacture and market Plavix in the United States. The headquarters for Bristol-Myers Squibb Company is located at 345 Park Avenue, New York, New York, 10145-0037.
- 3. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers

Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey 08807-0912.

- 4. Defendant, Sanofi-Aventis U.S., Inc., is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc., is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.
- 5. Defendant, Sanofi-Synthelabo, Inc., is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York, 10016. Sanofi-Synthelabo, Inc., did business as Sanofi Pharmaceuticals, Inc., and was the sponsor for Plavix application for Plavix. Sanofi-Synthelabo, Inc., is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., that was instrumental in bringing Plavix to market.
- 6. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo, Inc., will be collectively referred to as "Sanofi" in this complaint.

II.

## JURISDICTION AND VENUE

7. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over the Defendants, because

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27 28 development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and sale of Plavix.

- At all material times, Plavix was designed, developed, manufactured, tested, 11. packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants.
- The Sanofi Defendants and BMS co-developed Plavix, applying in April 12. 1997, for a rare priority regulatory review, by the U.S. Food and Drug Administration (FDA), which cleared the way for the Defendants to bring Plavix to market in November 1997.
- The rush to obtain FDA approval of Plavix is indicative of Defendants' 13. emphasis on marketing and profit making over patient safety.
- Plavix was heavily marketed directly to consumers through television, 14. magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.
- The truth is that BMS and Sanofi always knew, or if they had paid attention 15. to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.

- 16. Still, BMS and Sanofi continued to exaggerate the results of their own studies and made false statements in their advertising and promotional materials for the purpose of increasing their profits from Plavix sales.
- 17. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, Plavix, was the sixth top selling drug in the United States and the Defendants enjoy annual sales of Plavix totaling \$3,800,000,000.00 (3.8 billion dollars).
- 18. BMS and Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about Plavix they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promotional practices.
- 19. As examples, in 1998, the FDA requested the Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants' marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA approved dosage nearly four (4) times that of other applications be given.
- 20. That same FDA warning criticized the Defendants' attempts at overpromotion of Plavix for unapproved use for lacking fair balance and failing to disclose
  any of the risks associated with its use. In particular, the FDA criticized that the
  Defendants were claiming to physicians, in their promotional letter, that Plavix was safe
  for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix.
  In particular, its safety when combined with aspirin (known as "dual therapy") had not
  been established, yet Defendants were making a claim that the dual combination therapy

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of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance Trial), which was reported in *The New England Journal of Medicine*, April 20, 2006.

- 21. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.
- Undaunted, the Defendants were back in the business of hiding bad facts 22. about their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced to order Defendants to immediately cease distribution of promotional materials that made unsubstantiated claims about Plavix and was misleading. Specifically, the Defendants' promotional materials mislead consumers about their own study, called CAPRIE (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events). While the Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin-providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

- 23. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.
- 24. Defendants, through, their drug representatives, and their promotional efforts, have encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use Plavix for unapproved applications.
- 25. The result is that physicians are prescribing Plavix to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars (\$4.00) a day for a dose of Plavix.
- 26. Defendants' nearly eight-year run of lying to physicians and to the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is Plavix not worth its high price—it is dangerous.
- 27. The Chan study, written about in *The New England Journal of Medicine*, and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertion that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus

only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that the patients would not erroneously believe that Plavix is safer on the stomach than aspirin.

- 28. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four-dollar (\$4.00) a day Plavix pill that greatly increases the risk of stomach bleeding.
- 29. Most recently, the CHARISMA trial uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.
- 30. Despite the growing body of scientific knowledge that the four-dollar (\$4.00) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.
- 31. Plaintiff, Beatrice Mills, was prescribed Plavix on or about January 7, 2009, by Dr. L. Xavier and continued on Plavix thereafter. On January 12, 2009, Plaintiff began to hemorrhage and sought medical treatment at the Mercy Gilbert Hospital. On January

20, 2009, Beatrice Mills was released from Mercy Gilbert Hospital. Subsequently, Beatrice Mills was re-admitted to Mercy Gilbert Hospital, on January 25, 2009, for continual problems relating to clotting and bleeding. Beatrice Mills was finally discharged from the hospital on January 30, 2009.

- 32. The label for Plavix drug products, known as the "Package Insert" was developed by the Defendants and accompanied all Plavix prescription drug products and/or samples and was published in the Physician's Desk Reference.
- 33. Drug labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions and side effects.
- 34. Defendants failed to fully, truthfully and accurately communicate the safety and efficacy of Plavix drug products and intentionally and fraudulently mislead the medical community, physicians, Plaintiff's physicians and Plaintiff about the risks associated with Plavix.
- Defendants fraudulently and aggressively promoted Plavix drug products to physicians for use in patients, such as Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures, leaflets and hand outs as these materials downplayed the significance of the adverse effects of Plavix.
- 36. At all relevant times hereto, Defendants did not investigate the accuracy of the Plavix drug product labeling.

- 37. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of the true effects described above to the FDA, healthcare providers and patients, including Plaintiff.
- 38. Defendants were required to report literature, papers; and, to undertake action to reflect truthful and accurate information in its labeling and promotional materials and failed to do so.

#### IV. ALLEGATIONS

- 39. Defendants are under a duty to ensure that their Plavix drug product labels are accurate.
- 40. Defendants failed to ensure its Plavix warnings to the medical community were accurate and adequate and breached this duty.
- 41. Defendants have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Plavix drug products, the medical community, Plaintiff's physician, Plaintiff and other foreseeable users and failed to fulfill this duty.
- 42. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Plavix, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their Plavix drug products.
  - 43. Defendants breached their duty to the medical community, Plaintiff's

physicians, Plaintiff, and other foreseeable users similarly situated because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Plavix drug products to said persons and other foreseeable users.

- 44. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report significant data concerning the lack of efficacy and side effects associated with Plavix.
- 45. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in Plavix drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff, plaintiff's physicians and other foreseeable users.
- 46. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by Plavix drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Plaintiff's physicians, Plaintiff and other foreseeable users about the safety and efficacy of Plavix drug products.
- 47. At all times material hereto, Defendants knew or should have known that physicians and plaintiff were unaware of or did not fully appreciate the seriousness of the risks associated with use of Plavix drug products and the lack of benefit.

- 48. At the time Defendants made the above-described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.
- 49. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Plavix.
- 50. In doing the acts alleged in this Complaint, Defendants acted with oppression, fraud, and malice and Plaintiff's are therefore entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future.
- 51. As a proximate result of the fraud and deceit of Defendants, Plaintiff sustained the injuries and damages as described in this Complaint.
- 52. Defendants have an absolute duty to disclose the true facts regarding the safety of Plavix drug products to the medical community, to physicians and their patients, which they negligently and/or intentionally failed to do.
- 53. Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of Plavix were accurate which it negligently and/or intentionally failed to do.
- 54. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Defendants.
  - 55. Defendants' misrepresentations or omissions were a cause in fact and a

1 proximate cause of Plaintiff's damages. 2 A reasonably competent physician who prescribed Plavix and a reasonably 56. 3 competent Plaintiff who consumed Plavix would not realize its dangerous condition. 4 The reasonably foreseeable use of Plavix drug products involved substantial 57. 5 dangers not readily recognizable by Plaintiff's physicians, who acted as ordinary, 6 7 reasonable and prudent physicians would, when prescribing Plavix to ordinary, reasonable 8 and prudent patients, like Plaintiff. 9 58. As a direct and proximate result of the aforesaid acts of and/or omissions by the 10 11 Defendants, Plaintiff, has: 12 Suffered severe and permanent injuries, which she will be forced to (a) endure for the remainder of her life; 13 Suffered physical impairment and disfigurement; and (b) 14 Suffered physical pain and suffering; (c) 15 Suffered mental pain and suffering; and (d) 16 Suffered from loss of enjoyment of life; and (e) 17 Incurred and will continue to incur various sums of money for past, (f) 18 present and future medical expenses associated with monitoring and treating Plaintiffs injuries; and 19 Incurred attorney's fees and expenses of litigation related to this (g) 20 action. 21 Defendants' actions were intentional, willful, wanton, oppressive, malicious, 59. 22 and reckless, evidencing such an entire want of care as to raise the presumption of a 23 conscious indifference to the consequences and acted only out of self interest and personal 24 gain and evidenced a specific intent to cause harm to Plaintiff. 25 26 Plaintiff's serious and permanent injuries came about as a foreseeable and 60. 27 proximate result of the Defendants' dissemination of inaccurate, misleading, materially 28

incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of Plavix to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of Plavix.

- 61. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries suffered caused by the ingestion of Defendants' Plavix drug products.
- 62. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through failing to disclose, for eight years, the truth about the safety and efficacy of Plavix, to Plaintiff's physicians and/or Plaintiff, and misrepresenting Plavix as safe and efficacious for its intended use, actively concealed from said individuals the true risks associated with the use of Plavix drug products.
- 63. Plaintiff had no knowledge that Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action.
- 64. Neither, Plaintiff, nor Plaintiff's physicians, could have possibly determined the nature, extent and identity of related health risks associated with Plavix, and reasonably relied on Defendants to disseminate truthful and accurate safety and efficacy information about its drug and warn of the side effects complained of herein.
  - 65. Furthermore, Defendants are estopped from relying on any statute of

limitations because of their fraudulent concealment of the defective nature of Plavix. Defendants were under a duty to disclose the true character, quality, and nature of Plavix because this was non-public information over which the Defendants have, and continue to have, exclusive control, and because Defendants knew this information was not available to the Plaintiff or their physicians. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

#### **COUNT I**

## STRICT PRODUCTS LIABILITY

## (Failure to Warn)

- 66. Plaintiffs incorporate by reference paragraphs 1 through 107 above, as if fully set forth.
- 67. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling Plavix.
  - 68. Plavix is defective and unreasonably dangerous to consumers.
- 69. At all times mentioned in this Complaint Plavix was defective and/or unreasonably dangerous to Plaintiffs and other foreseeable users at the time it left the control of the Defendants.
- 70. Plavix is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.
- 71. The foreseeable risks associated with the design or formulation of Plavix, include, but are not limited to, the fact that the design or formulation of Plavix is more

dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.

- 72. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of Arizona and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.
- 73. Defendants, developed, marketed and distributed Plavix drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of Plavix.
- 74. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that Plavix created a high risk of bodily injury and serious harm.
- 75. The dangerous propensities of Plavix drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold Plavix, and not known to ordinary physicians who would be expected to prescribe Plavix for their patients.
- 76. Plavix drug products, as distributed, were defective and unreasonably dangerous inasmuch as Plavix were not accompanied by warnings and instructions that were appropriate and adequate to render Plavix reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of Plavix.
- 77. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of Plavix drug products with knowledge that consumers would be exposed to serious danger.

1	78. At al	l times material to this action, Plavix was designed, developed,			
2	manufactured, teste	d, packaged, promoted, marketed, distributed, labeled, and/or sold by			
3	Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was				
5	placed in the stream of commerce in ways that include, but are not limited to one or more of				
6	the particulars:				
7	(a)	At the time Plavix left the control of the Defendants Plavix was			
8		defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because			
9		Plavix breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiffs' physicians			
11		justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiffs seek recovery herein.			
12	(b)	Playix drug products were not reasonably safe as designed, taking			
13	, ,	into account the foreseeable risks involved in its use at the time			
14		clearly outweighed the utility of Plavix therapy or its therapeutic benefits, and subjected Plaintiffs to the risk of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and even			
15		death in an unacceptably high number of its users;			
16 17	(c)	At the time Plavix left the control of the Defendants Plavix possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or			
18		instructions that were known or reasonably scientifically knowable at the time Playix left the possession of the Defendants. Specifically,			
19		although the Defendants were well aware that Plavix products could potentially cause severe side effects.			
20	(d)	The Defendants' warnings or instructions were not of a nature that a			
21		reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger.			
22		There were no warnings or instructions that communicate sufficient information on the dangers and safe use of Plavix taking into account			
23		the characteristics of the Plavix, and/or the ordinary knowledge common to the physician who prescribes and the consumer who			
24		purchases Plavix, such as the Plaintiffs.			
25	(e)	Plavix manufactured and supplied by the Defendants were further defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the			
26		risks of injury from Plavix drug products associated with the use as commonly prescribed, Defendants failed to promptly respond to and			
27		adequately warn about the risks of suffering avoidable heart attacks,			
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its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.

- 85. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of Plavix. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.
- 86. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

## COUNT II

## STRICT PRODUCT LIABILITY

## (Pursuant to Restatement Second of Torts 402(a) (1965)

- 87. Plaintiff repeats, re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.
  - 88. The Plavix manufactured and/or distributed and/or supplied by defendants was

defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceed the benefits associated with the design and formulation of the drug.

- 89. Alternatively, the Plavix manufactured and/or distributed and/or supplied by defendants was defective in design or formulation in that, when it left the hands of the manufactures and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of acute coronary syndrome, recent myocardial infarction, or established peripheral arterial disease.
  - 90. There existed, at all times material hereto, safer alternative medications.
- 91. Defendant did not perform adequate testing upon PLAVIX. Adequate testing would have revealed that PLAVIX causes serious adverse effects as described in this complaint with respect to which full and proper warnings accurately and fully reflecting symptoms, scope, and severity should have been made.
- 92. The PLAVIX manufactured, designed, marketed, distributed and/or sold by defendants was unaccompanied by proper and adequate warnings regarding adverse effects associated with the use of PLAVIX and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.
- 93. Defendant did not warn the FDA of material facts regarding the safety and efficacy of PLAVIX, which facts defendant knew or should have known.
  - 94. The PLAVIX manufactured and/or distributed and/or supplied by defendant

was defective due to inadequate post-marketing warning or instructions, because, after the defendant knew or should have known of the risk of injury from PLAVIX, they failed to provide adequate warnings to users or consumer of PLAVIX and continued to promote PLAVIX.

95. As a result of the defective condition of PLAVIX, Plaintiff has suffered damage and injury.

## **COUNT III**

## INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

- 96. Plaintiff repeats, and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 97. Through intentional, reckless, and extreme conduct Defendants knowingly denied Plaintiff adequate opportunity in measuring the level of risk related to Plavix drug products. By withholding information of known design and manufacturing defects and concealing those fatal problems, Defendants created a false sense of security for Plaintiff, who assumed the reasonable safety of Plavix.
- 98. Defendants' conduct of intentional omission, concealment, and failure to warn of the design and manufacturing defects caused Plaintiff to suffer injuries, harm, and economic loss as alleged herein, including a permanent and substantial injuries, and expenses attributable to Plaintiff's condition.
- 99. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will

continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

100. The injuries described herein entitle Plaintiff to compensatory damages and equitable and declaratory relief, along with all appropriate damages according to proof.

## **COUNT IV**

## NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

- 101. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs as if fully set forth herein.
- 102. Defendants negligently failed to disclose or warn of the inherent risks and defects associated with the use of Plavix drug products. Defendants negligently manufactured, distributed, marketed, and sold Plavix to Plaintiff, while knowingly concealing design, manufacturing and safety defects, and misrepresenting the risks of severe side effects, quality, safety, and efficacy of Plavix.
- 103. Defendants' negligent conduct inflicted Plaintiff with severe emotional distress through Plaintiff's subsequent injuries resulting from the use of Plavix.
- 104. Defendants' negligent conduct of willful omission and concealment of design, manufacturing and safety defects in order to induce ingestion of their Plavix drug products caused Plaintiff severe emotional distress.
  - 105. As a direct and proximate result of the wrongful acts of the Defendants,

Plaintiff developed severe side effects as described herein and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

#### **COUNT V**

#### **COMMON LAW FRAUD**

- 106. Plaintiff repeats, and re-alleges the allegations of the prior paragraphs as if set forth at length herein.
- 107. Defendant made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendant had in its possession adverse drug event reports, drug studies and other documentation about PLAVIX and yet made the following misrepresentations:
  - a. Misrepresentations regarding the frequency of PLAVIX related adverse event reports or occurrences in the PLAVIX label, package, insert or PDR label;
  - b. Misrepresentations as to existence, occurrence and frequency of occurrences, severity and extent of the overall risks of PLAVIX;
  - c. Misrepresentations as to the efficacy of PLAVIX;
  - d. Misrepresentations as to the number of adverse events, deaths and birth defects, reported with the use of PLAVIX;

1	e. Misrepre	esentations regarding the nature, seriousness, and severity of adverse	
2	events re	ported with the use of PLAVIX.	
3	108. Defenda	ants intended that these misrepresentations be relied upon by	
4   5	physicians, including	Plaintiff's physicians, healthcare providers and consumers. Plaintiff	
6	did rely upon the misrepresentations that caused Plaintiff's injuries.		
7	COUNT VI		
8		NEGLIGENCE	
9		TODOLIVOE	
10	109. Plaintiff	repeats and re-alleges the allegations of the prior paragraphs as if	
1	fully set forth at length herein.		
12	110. Defenda	nts owed Plaintiff legal duties in connection with its development,	
13	manufacture and distribution of PLAVIX. Defendants breached those duties, proximately		
14   15	causing Plaintiff's injuries. Specifically, Defendants failed to meet its duty to use reasonable		
16	care in the testing, of	creating, designing, manufacturing, labeling, packaging, marketing,	
17			
18			
19			
20	k	Failure to adequately warn Plaintiff and Plaintiff's physicians of the mown or reasonably foreseeable danger that Plaintiff would suffer a	
21		erious injury or death by ingesting PLAVIX;	
22	l k	Failure to adequately warn Plaintiff and Plaintiff's physicians of the mown or reasonably foreseeable danger that Plaintiff would suffer a erious injury or death by ingesting PLAVIX in unsafe doses;	
23		Failure to use reasonable care in testing and inspecting PLAVIX so as	
24 25	t	o ascertain whether or not it was safe for the purpose for which it was lesigned, manufactured and sold;	
2 <i>5</i> 26	(d) I	Failure to use reasonable care in implementing and/or utilizing a easonably safe design in the manufacture of PLAVIX;	
27	1	Failure to use reasonable care in the process of manufacturing PLAVIX	
28	(e) l	n a reasonably safe condition for the use for which it was intended;	
	I		

	(f) Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using PLAVIX in unsafe doses;	
	(g) Such further acts and/or omissions that may be proven at trial.	
111.	The above-described acts and/or omissions of Defendant were a direct and	
proximate cause of the severe, permanent and disabling injuries and resulting damages to		
Plaintiff.		
	COUNT VII	
	NEGLIGENT MISREPRESENTATION	
	NEGLIGENT MISKEI RESERVATION	
112.	Plaintiff repeat and re-allege the allegation of the prior paragraphs as if fully	
set forth here	in.	
113.	Defendant failed to communicate to Plaintiff and/or the general public that the	
ingestion of	PLAVIX could cause serious injuries after it became aware of such risks.	
Instead, Defendant represented in its marketing that PLAVIX was safe and effective.		
114.	Plaintiff brings this cause of action against Defendant under the theory of	
negligent mi	srepresentation for the following reasons:	
	To a local to the late of the country appropriately on distributors	
a.	Defendant, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about PLAVIX in	
	that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively,	
	Defendant made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;	
b.	The above misrepresentations were made to Plaintiff, as well as the general public;	
c.	Plaintiff and their healthcare providers justifiably relied on Defendant's	
	misrepresentations; and	
d.	Consequently, Plaintiff ingested PLAVIX to Plaintiff's detriment.	
	proximate car Plaintiff.  112.  set forth here 113.  ingestion of Instead, Defe	

Defendant's negligent misrepresentations proximately caused Plaintiff's 1 injuries and monetary loss. 2 3 COUNT VIII 4 FRADULENT MISREPRESENTATION 5 Plaintiff repeats and re-alleges the allegation of the prior paragraphs as if fully 6 115. 7 set forth herein. 8 Defendant is engaged in the business of selling PLAVIX. By advertising, 116. 9 labels, or otherwise, Defendant has made to Plaintiff, and the public, a misrepresentation of a 10 material fact concerning the character or quality of PLAVIX. 11 12 Plaintiff justifiably relied on Defendant's misrepresentation in purchasing 117. 13 Plaintiff has suffered physical harm proximately caused by Defendant's PLAVIX. 14 misrepresentations regarding the character or quality of PLAVIX. 15 COUNT IX 16 17 **EXPRESS WARRANTY** 18 Plaintiff repeats and re-alleges the allegation of the prior paragraphs as if fully 118. 19 set forth herein. 20 Defendants is a merchant and/or seller of PLAVIX. Defendants sold Plavix to 119. 21 22 consumers, including Plaintiff, for the ordinary purpose for which consumers use such drugs. 23 Defendants made representations to Plaintiff about the quality or characteristics of PLAVIX 24 by affirmation of fact, promise and/or description. The representation by Defendants 25 became part of the basis of the bargain between Defendants and Plaintiffs. PLAVIX did not 26 27 comport with the representations made by Defendants in that it was not safe for the use for 28

which it was marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

## **COUNT X**

#### **IMPLIED WARRANTY**

120. Plaintiff repeats and re-alleges the allegation of the prior paragraphs as if fully set forth herein.

## A. WARRANTY OF MERCHANTABILITY

PLAVIX from Defendant and used PLAVIX for the ordinary purpose for which consumers use it. At the time it was purchased by Plaintiff, PLAVIX was not fit for the ordinary purpose for which such drugs are used. PLAVIX was not fit for the ordinary purpose for which such drugs are used. PLAVIX was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely. Defendant's breach of its implied warranty of merchantability caused Plaintiff's injuries and monetary losses.

## **B. WARRANTY OF FITNESS**

- 122. Defendants sold PLAVIX to Plaintiff with the knowledge that Plaintiff was purchasing PLAVIX for a particular purpose. Further Defendants, knew, or should have known, that Plaintiff was relying on Defendant's skill or judgment to select goods fit for Plaintiff's purpose.
- 123. Defendant delivered goods that were unfit for Plaintiff's particular purpose, and thus breached its implied warranty of fitness. Defendant's failure to select and sell a product, which was reasonably safe for its intended use proximately, caused Plaintiff's

injuries and monetary losses. THEREFORE, the Plaintiff demands judgment as to all counts in Plaintiff's favor and against DEFENDANTS in a sum in excess of the jurisdictional requirement of this court; for costs herein incurred; attorney's fees; for such other and further relief as this Court deems just and proper; and demands that the issues herein contained be tried to a jury. **DATED** this 19<sup>th</sup> day of January, 2011. By \_\_/s/Jeffrey B. Miller Jeffrey B. Miller, Esq. MILLER WEBER KORY LLP 1112 East Washington Street Phoenix, Arizona 85034 Attorney for Plaintiff **ORIGINAL** of the foregoing electronically filed @ https://efiling.clerkofcourt.maricopa.gov this 19th day of January, 2011, with Maricopa County Superior Court By /s/Boo DeMarchi 

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MICHAEL K. JEANES Clerk of the Superior By Carrie Allen, Deput Date 01/13/2011 Time 16:19 Description Gabriel V. Kory, # 022536 gabe@mwkfirm.com MILLER WEBER KORY LLP 1112 East Washington Street Phoenix, Arizona 85034 (602) 648-4045 (602) 340-1896 (fax) Attorneys for Plaintiffand- P. ANN TRANTHAM, ESQ., State Bar #30972 1901 Texas Street Natchitoches, LA 71457 Telephone: (318) 352-5999 Email: patrantham@cp-tel.net robertsalim@cp-tel.net Pro Hac to Be Submitted  IN SUPERIOR COURT FOR THE STATE OF ARIZONA IN AND FOR THE COUNTY OF MARICOPA  BEATRICE MILLS, Plaintiff,	Court y 5:30 Amount				
17 18 19	v.  BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and SANOFI-SYNTHELABO, INC.	15				
20	Defendants.					
21	}					
22	<u>COMPLAINT</u>					
23	COMES NOW Beatrice Mills, hereinafter referred to as the "Plaintiff" who	files this				
24	Complaint, complaining of and for her cause of action against, BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS, U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., AND					
25						
26	SANOFI-SYNTHELABO, INC., the Plaintiffs, by and through their undersigned at					
27	their Complaint against Defendants, state and allege as follows:					
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	1					

This action is brought by Plaintiff seeking damages for personal injuries and economic damages suffered as a result of a defective and dangerous pharmaceutical product, PLAVIX. Plaintiff's damages arose as a result of her ingestion of Defendants PLAVIX drug which was manufactured, marketed, distributed and sold by Defendants and/or Defendants representatives and placed in the stream of commerce in this state by Defendants.

I.

## **PARTIES**

#### **PLAINTIFFS**

1. Plaintiff, Beatrice Mills, a natural person, is a citizen and resident of Fountain Hills, Maricopa County. Currently, Beatrice Mills resides at 16003 Burro Drive, Fountain Hills, Maricopa County, Arizona 85268, and was treated in said county for her injuries. At all times relative to this complaint, Beatrice Mills, resided at 739 Las Colinas, Chandler, Maricopa County, New Mexico, 85249.

#### **DEFENDANTS**

- Defendant, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to manufacture and market Plavix in the United States. The headquarters for Bristol-Myers Squibb Company is located at 345 Park Avenue, New York, New York, 10145-0037.
- 3. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey 08807-0912.

- 4. Defendant, Sanofi-Aventis U.S., Inc., is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc., is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.
- 5. Defendant, Sanofi-Synthelabo, Inc., is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York, 10016. Sanofi-Synthelabo, Inc., did business as Sanofi Pharmaceuticals, Inc., and was the sponsor for Plavix application for Plavix. Sanofi-Synthelabo, Inc., is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc., that was instrumental in bringing Plavix to market.
- 6. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo, Inc., will be collectively referred to as "Sanofi" in this complaint.

II.

## JURISDICTION AND VENUE

- 7. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over the Defendants, because Defendants are present in the State of Arizona such that requiring an appearance does not offend traditional notions of fair play and substantial justice.
- 8. This Court has personal jurisdiction over the Defendants, pursuant to, and consistent with, Arizona's long-arm statute and the Constitutional requirements of Due Process in that the Defendants acting through agents or apparent agents, committed one or more of the following:
  - a. Defendants transacted business in the State of Arizona;
  - b. Defendants owned, used or possessed real estate situated in the State of Arizona;
  - c. Defendants made or performed a contract or promise substantially connected within this state;

- The truth is that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.
- 16. Still, BMS and Sanofi continued to exaggerate the results of their own studies and made false statements in their advertising and promotional materials for the purpose of increasing their profits from Plavix sales.
- 17. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, Plavix, was the sixth top selling drug in the United States and the Defendants enjoy annual sales of Plavix totaling \$3,800,000,000.00 (3.8 billion dollars).
- 18. BMS and Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about Plavix they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promotional practices.
- 19. As examples, in 1998, the FDA requested the Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants' marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA approved dosage nearly four (4) times that of other applications be given.
- 20. That same FDA warning criticized the Defendants' attempts at over-promotion of Plavix for unapproved use for lacking fair balance and failing to disclose any of the risks associated with its use. In particular, the FDA criticized that the Defendants were claiming to physicians, in their promotional letter, that Plavix was safe for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix. In particular, its safety when combined

with aspirin (known as "dual therapy") had not been established, yet Defendants were making a claim that the dual combination therapy of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance Trial), which was reported in *The New England Journal of Medicine*, April 20, 2006.

- 21. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.
- their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced to order Defendants to immediately cease distribution of promotional materials that made unsubstantiated claims about Plavix and was misleading. Specifically, the Defendants' promotional materials mislead consumers about their own study, called CAPRIE (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events). While the Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin-providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.
- 23. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also

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misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.

- Defendants, through, their drug representatives, and their promotional efforts, have 24. encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use Plavix for unapproved applications.
- The result is that physicians are prescribing Plavix to people who could be cheaply 25. and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars (\$4.00) a day for a dose of Plavix.
- Defendants' nearly eight-year run of lying to physicians and to the public about the 26. safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is Plavix not worth its high price—it is dangerous.
- The Chan study, written about in The New England Journal of Medicine, and 27. named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertion that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that the patients would not erroneously believe that Plavix is safer on the stomach than aspirin.
- The Chan study also uncovered the fact that an aspirin a day plus esomeprazole 28. (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more

cost effective for the consumer than paying for a four-dollar (\$4.00) a day Plavix pill that greatly increases the risk of stomach bleeding.

- 29. Most recently, the CHARISMA trial uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.
- 30. Despite the growing body of scientific knowledge that the four-dollar (\$4.00) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.
- 21. Plaintiff, Beatrice Mills, was prescribed Plavix on or about January 7, 2009, by Dr. L. Xavier and continued on Plavix thereafter. On January 12, 2009, Plaintiff began to hemorrhage and sought medical treatment at the Mercy Gilbert Hospital. On January 20, 2009, Beatrice Mills was released from Mercy Gilbert Hospital. Subsequently, Beatrice Mills was readmitted to Mercy Gilbert Hospital, on January 25, 2009, for continual problems relating to clotting and bleeding. Beatrice Mills was finally discharged from the hospital on January 30, 2009.
- 32. The label for Plavix drug products, known as the "Package Insert" was developed by the Defendants and accompanied all Plavix prescription drug products and/or samples and was published in the Physician's Desk Reference.

- 33. Drug labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, efficacy, contraindications, warnings, precautions and side effects.
- 34. Defendants failed to fully, truthfully and accurately communicate the safety and efficacy of Plavix drug products and intentionally and fraudulently mislead the medical community, physicians, Plaintiff's physicians and Plaintiff about the risks associated with Plavix.
- 35. Defendants fraudulently and aggressively promoted Plavix drug products to physicians for use in patients, such as Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications, as well as other promotional materials including package inserts, physician desk reference, monographs and patient brochures, leaflets and hand outs as these materials downplayed the significance of the adverse effects of Plavix.
- 36. At all relevant times hereto, Defendants did not investigate the accuracy of the Plavix drug product labeling.
- 37. Defendants were negligent in failing to report published articles and overwhelming scientific evidence of the true effects described above to the FDA, healthcare providers and patients, including Plaintiff.
- 38. Defendants were required to report literature, papers; and, to undertake action to reflect truthful and accurate information in its labeling and promotional materials and failed to do so.

#### IV. ALLEGATIONS

- 39. Defendants are under a duty to ensure that their Plavix drug product labels are accurate.
- 40. Defendants failed to ensure its Plavix warnings to the medical community were accurate and adequate and breached this duty.

- 41. Defendants have a duty to conduct post market safety surveillance; to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Plavix drug products, the medical community, Plaintiff's physician, Plaintiff and other foreseeable users and failed to fulfill this duty.
- 42. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Plavix, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of their Plavix drug products.
- Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because Defendants failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Plavix drug products to said persons and other foreseeable users.
- 44. Defendants breached their duty to the medical community, Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report significant data concerning the lack of efficacy and side effects associated with Plavix.
- 45. Defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in Plavix drug product labels and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff, plaintiff's physicians and other foreseeable users.
- 46. At all times material hereto, Defendants were aware of the serious side effects described herein which were caused by Plavix drug products and failed to fulfill the obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians,

Plaintiff's physicians, Plaintiff and other foreseeable users about the safety and efficacy of Plavix drug products.

- 47. At all times material hereto, Defendants knew or should have known that physicians and plaintiff were unaware of or did not fully appreciate the seriousness of the risks associated with use of Plavix drug products and the lack of benefit.
- 48. At the time Defendants made the above-described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.
- 49. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendants' failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of Plavix.
- 50. In doing the acts alleged in this Complaint, Defendants acted with oppression, fraud, and malice and Plaintiff's are therefore entitled to punitive damages to deter Defendants and others from engaging in similar conduct in the future.
- 51. As a proximate result of the fraud and deceit of Defendants, Plaintiff sustained the injuries and damages as described in this Complaint.
- Defendants have an absolute duty to disclose the true facts regarding the safety of Plavix drug products to the medical community, to physicians and their patients, which they negligently and/or intentionally failed to do.
- 53. Defendants have a duty to ensure that they had a reasonable basis for making the representations regarding the safety; efficacy, risks and benefits of Plavix were accurate which it negligently and/or intentionally failed to do.

proximate result of the Defendants' dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the effects of exposure and ingestion of Plavix to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of Plavix.

- 61. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries suffered caused by the ingestion of Defendants' Plavix drug products.
- 62. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through failing to disclose, for eight years, the truth about the safety and efficacy of Plavix, to Plaintiff's physicians and/or Plaintiff, and misrepresenting Plavix as safe and efficacious for its intended use, actively concealed from said individuals the true risks associated with the use of Plavix drug products.
- 63. Plaintiff had no knowledge that Defendants was engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior to the commencement of this action.
- Neither, Plaintiff, nor Plaintiff's physicians, could have possibly determined the nature, extent and identity of related health risks associated with Plavix, and reasonably relied on Defendants to disseminate truthful and accurate safety and efficacy information about its drug and warn of the side effects complained of herein.
- 65. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the defective nature of Plavix. Defendants were under a duty to disclose the true character, quality, and nature of Plavix because this was non-

public information over which the Defendants have, and continue to have, exclusive control, and because Defendants knew this information was not available to the Plaintiff or their physicians. In addition, the Defendants are estopped from relying on any statute of limitations because of their concealment of these facts.

## **COUNT I**

#### STRICT PRODUCTS LIABILITY

#### (Failure to Warn)

- 66. Plaintiffs incorporate by reference paragraphs 1 through 107 above, as if fully set forth.
- 67. At all relevant times the Defendants were engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling Plavix.
  - 68. Plavix is defective and unreasonably dangerous to consumers.
- 69. At all times mentioned in this Complaint Plavix was defective and/or unreasonably dangerous to Plaintiffs and other foreseeable users at the time it left the control of the Defendants.
- 70. Plavix is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceed the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.
- 71. The foreseeable risks associated with the design or formulation of Plavix, include, but are not limited to, the fact that the design or formulation of Plavix is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.
- 72. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of Arizona and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.

- 73. Defendants, developed, marketed and distributed Plavix drug products to the general public even after learning of the design and manufacturing defects that threatened the intended use of Plavix.
- 74. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that Plavix created a high risk of bodily injury and serious harm.
- 75. The dangerous propensities of Plavix drug products were known or scientifically knowable, through appropriate research and testing, to the Defendants at the time said Defendants distributed, supplied, or sold Plavix, and not known to ordinary physicians who would be expected to prescribe Plavix for their patients.
- 76. Plavix drug products, as distributed, were defective and unreasonably dangerous inasmuch as Plavix were not accompanied by warnings and instructions that were appropriate and adequate to render Plavix reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of Plavix.
- 77. In order to advance Defendant's own pecuniary interests, Defendants intentionally proceeded with the manufacturing, the sale and distribution, and marketing of Plavix drug products with knowledge that consumers would be exposed to serious danger.
- 78. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a "defective" and "unreasonably dangerous" condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to one or more of the particulars:
  - (a) At the time Plavix left the control of the Defendants Plavix was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because Plavix breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiffs' physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiffs seek recovery herein.

Plavix drug products were not reasonably safe as designed, taking into (b) 1 account the foreseeable risks involved in its use at the time Plavix left the possession of the Defendants, and that such risks clearly outweighed the 2 utility of Plavix therapy or its therapeutic benefits, and subjected Plaintiffs to the risk of suffering avoidable heart attacks, strokes, blood disorders, 3 abnormal bleeding and even death in an unacceptably high number of its 4 users; At the time Plavix left the control of the Defendants Plavix possessed a 5 (c) dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were 6 known or reasonably scientifically knowable at the time Plavix left the possession of the Defendants. Specifically, although the Defendants were 7 well aware that Plavix products could potentially cause severe side effects. 8 The Defendants' warnings or instructions were not of a nature that a (d) reasonably prudent drug company in the same or similar circumstances 9 would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and 10 safe use of Plavix taking into account the characteristics of the Plavix, and/or the ordinary knowledge common to the physician who prescribes 11 and the consumer who purchases Plavix, such as the Plaintiffs. 12 Plavix manufactured and supplied by the Defendants were further defective (e) due to inadequate post-marketing warning or instruction because, after the 13 Defendants knew or should have known of the risks of injury from Plavix drug products associated with the use as commonly prescribed, Defendants 14 failed to promptly respond to and adequately warn about the risks of suffering avoidable heart attacks, strokes, blood disorders, abnormal 15 bleeding and death associated with the use of Plavix. 16 When placed in the stream of commerce of commerce, Plavix was (f) defective in design and formulation, making the use of Plavix more 17 dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other similar drugs on the market 18 including Aspirin; 19 (g) Plavix was insufficiently tested. 20 The Defendants knew, or in light of reasonably available scientific knowledge should 79. 21 have known, about the danger that caused the injuries for which Plaintiff seeks recovery. 22 The Defendants knew or in light of reasonably available scientific knowledge should 80. 23 have known about the danger associated with use of Plavix that caused the damages for which 24 25 Plaintiff seeks recovery. 26 The reasonably foreseeable use of Plavix involved substantial dangers not readily 81. 27 recognizable by the ordinary physician who prescribed Plavix or the patient, including Plaintiff, who 28

consumed Plavix drug products.

- 82. The Defendants knew that Plavix drug products were to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that Plavix were not properly prepared nor accompanied by adequate warnings of the dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.
- 83. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of Defendants' Plavix drug products, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.
- 84. The above defects caused serious injuries to Plaintiff when Plavix was used in its intended and foreseeable manner, and in the manner recommended by the Defendants and/or in a non-intended manner that was reasonably foreseeable.
- 85. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of Plavix. These safer designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.
- 86. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff suffered severe and irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the

evidence.

## COUNT II

#### STRICT PRODUCT LIABILITY

# (Pursuant to Restatement Second of Torts 402(a) (1965)

- 87. Plaintiff repeats, re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 88. The Plavix manufactured and/or distributed and/or supplied by defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceed the benefits associated with the design and formulation of the drug.
- 89. Alternatively, the Plavix manufactured and/or distributed and/or supplied by defendants was defective in design or formulation in that, when it left the hands of the manufactures and/or suppliers and/or distributors, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than alternative drugs available for the treatment of acute coronary syndrome, recent myocardial infarction, or established peripheral arterial disease.
  - 90. There existed, at all times material hereto, safer alternative medications.
- 91. Defendant did not perform adequate testing upon PLAVIX. Adequate testing would have revealed that PLAVIX causes serious adverse effects as described in this complaint with respect to which full and proper warnings accurately and fully reflecting symptoms, scope, and severity should have been made.
- 92. The PLAVIX manufactured, designed, marketed, distributed and/or sold by defendants was unaccompanied by proper and adequate warnings regarding adverse effects

associated with the use of PLAVIX and the severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of adverse effects and did not accurately relate the lack of efficacy.

- 93. Defendant did not warn the FDA of material facts regarding the safety and efficacy of PLAVIX, which facts defendant knew or should have known.
- 94. The PLAVIX manufactured and/or distributed and/or supplied by defendant was defective due to inadequate post-marketing warning or instructions, because, after the defendant knew or should have known of the risk of injury from PLAVIX, they failed to provide adequate warnings to users or consumer of PLAVIX and continued to promote PLAVIX.
- 95. As a result of the defective condition of PLAVIX, Plaintiff has suffered damage and injury.

# **COUNT III**

# INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

- 96. Plaintiff repeats, and re-alleges the allegations set forth in the paragraphs above as if fully set forth herein.
- 97. Through intentional, reckless, and extreme conduct Defendants knowingly denied Plaintiff adequate opportunity in measuring the level of risk related to Plavix drug products. By withholding information of known design and manufacturing defects and concealing those fatal problems, Defendants created a false sense of security for Plaintiff, who assumed the reasonable safety of Plavix.
- 98. Defendants' conduct of intentional omission, concealment, and failure to warn of the design and manufacturing defects caused Plaintiff to suffer injuries, harm, and economic loss as alleged herein, including a permanent and substantial injuries, and expenses attributable to Plaintiff's condition.

- 99. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein, and suffered irreparable bodily injury; suffered and will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.
- 100. The injuries described herein entitle Plaintiff to compensatory damages and equitable and declaratory relief, along with all appropriate damages according to proof.

#### **COUNT IV**

#### **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

- 101. Plaintiff repeats and re-alleges the allegations set forth in the paragraphs as if fully set forth herein.
- Defendants negligently failed to disclose or warn of the inherent risks and defects associated with the use of Plavix drug products. Defendants negligently manufactured, distributed, marketed, and sold Plavix to Plaintiff, while knowingly concealing design, manufacturing and safety defects, and misrepresenting the risks of severe side effects, quality, safety, and efficacy of Plavix.
- 103. Defendants' negligent conduct inflicted Plaintiff with severe emotional distress through Plaintiff's subsequent injuries resulting from the use of Plavix.
- 104. Defendants' negligent conduct of willful omission and concealment of design, manufacturing and safety defects in order to induce ingestion of their Plavix drug products caused Plaintiff severe emotional distress.
- 105. As a direct and proximate result of the wrongful acts of the Defendants, Plaintiff developed severe side effects as described herein and suffered irreparable bodily injury; suffered and

will continue to suffer great pain of body and mind; suffered and will continue to suffer great embarrassment and humiliation; suffered and will continue to suffer permanent impairment to Plaintiff's earnings capacity; incurred and will continue to incur expenses for medical treatment of Plaintiff's injuries; suffered and will continue to suffer the loss of enjoyment of life and have been otherwise damaged to be further shown by the evidence.

#### **COUNT V**

#### **COMMON LAW FRAUD**

- 106. Plaintiff repeats, and re-alleges the allegations of the prior paragraphs as if set forth at length herein.
- 107. Defendant made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendant had in its possession adverse drug event reports, drug studies and other documentation about PLAVIX and yet made the following misrepresentations:
  - a. Misrepresentations regarding the frequency of PLAVIX related adverse event reports
    or occurrences in the PLAVIX label, package, insert or PDR label;
  - b. Misrepresentations as to existence, occurrence and frequency of occurrences, severity and extent of the overall risks of PLAVIX;
  - c. Misrepresentations as to the efficacy of PLAVIX;
  - d. Misrepresentations as to the number of adverse events, deaths and birth defects,
     reported with the use of PLAVIX;
  - e. Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of PLAVIX.
- 108. Defendants intended that these misrepresentations be relied upon by physicians, including Plaintiff's physicians, healthcare providers and consumers. Plaintiff did rely upon the

misrepresentations that caused Plaintiff's injuries. 1 2 **COUNT VI** 3 NEGLIGENCE 4 Plaintiff repeats and re-alleges the allegations of the prior paragraphs as if fully set 109. 5 forth at length herein. 6 Defendants owed Plaintiff legal duties in connection with its development, 110. 7 manufacture and distribution of PLAVIX. Defendants breached those duties, proximately causing 8 Plaintiff's injuries. Specifically, Defendants failed to meet its duty to use reasonable care in the 9 10 testing, creating, designing, manufacturing, labeling, packaging, marketing, selling and warning of 11 PLAVIX. Defendant is liable for acts and/or omissions amounting to negligence, gross negligence 12 and/or malice, including, but not limited to the following: 13 Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or (a) 14 reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting PLAVIX; 15 Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or (b) reasonably foreseeable danger that Plaintiff would suffer a serious injury or 16 death by ingesting PLAVIX in unsafe doses; 17 Failure to use reasonable care in testing and inspecting PLAVIX so as to (c) ascertain whether or not it was safe for the purpose for which it was designed, 18 manufactured and sold; 19 Failure to use reasonable care in implementing and/or utilizing a reasonably (d) 20 safe design in the manufacture of PLAVIX; 21 Failure to use reasonable care in the process of manufacturing PLAVIX in a (e) reasonably safe condition for the use for which it was intended; 22 Failure to use reasonable care in the manner and method of warning Plaintiff (f) 23 and Plaintiff's physicians as to the danger and risks of using PLAVIX in unsafe doses: 24 Such further acts and/or omissions that may be proven at trial. (g) 25 The above-described acts and/or omissions of Defendant were a direct and proximate 111. 26 cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff. 27 COUNT VII 28

#### NEGLIGENT MISREPRESENTATION 1 2 Plaintiff repeat and re-allege the allegation of the prior paragraphs as if fully set forth 112. 3 herein. 4 Defendant failed to communicate to Plaintiff and/or the general public that the 113. 5 ingestion of PLAVIX could cause serious injuries after it became aware of such risks. Instead, 6 Defendant represented in its marketing that PLAVIX was safe and effective. 7 Plaintiff brings this cause of action against Defendant under the theory of negligent 114. 8 9 misrepresentation for the following reasons: 10 a. Defendant, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about PLAVIX in that they 11 made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendant made such 12 misrepresentations without exercising reasonable care to ascertain the accuracy of 13 these representations; 14 b. The above misrepresentations were made to Plaintiff, as well as the general public; 15 c. Plaintiff and their healthcare providers justifiably relied on Defendant's misrepresentations; and 16 d. Consequently, Plaintiff ingested PLAVIX to Plaintiff's detriment. 17 Defendant's negligent misrepresentations proximately caused Plaintiff's injuries and monetary 18 loss. 19 20 **COUNT VIII** 21 FRADULENT MISREPRESENTATION 22 Plaintiff repeats and re-alleges the allegation of the prior paragraphs as if fully set 115. 23 forth herein. 24 Defendant is engaged in the business of selling PLAVIX. By advertising, labels, or 116. 25 otherwise, Defendant has made to Plaintiff, and the public, a misrepresentation of a material fact 26 concerning the character or quality of PLAVIX. 27 Plaintiff justifiably relied on Defendant's misrepresentation in purchasing PLAVIX. 28 117.

Plaintiff has suffered physical harm proximately caused by Defendant's misrepresentations regarding the character or quality of PLAVIX.

#### **COUNT IX**

#### **EXPRESS WARRANTY**

- 118. Plaintiff repeats and re-alleges the allegation of the prior paragraphs as if fully set forth herein.
- Defendants is a merchant and/or seller of PLAVIX. Defendants sold Plavix to consumers, including Plaintiff, for the ordinary purpose for which consumers use such drugs. Defendants made representations to Plaintiff about the quality or characteristics of PLAVIX by affirmation of fact, promise and/or description. The representation by Defendants became part of the basis of the bargain between Defendants and Plaintiffs. PLAVIX did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

#### COUNT X

#### IMPLIED WARRANTY

120. Plaintiff repeats and re-alleges the allegation of the prior paragraphs as if fully set forth herein.

## A. WARRANTY OF MERCHANTABILITY

121. Defendants are merchant and/or sellers of PLAVIX. PLAINTIFF purchased PLAVIX from Defendant and used PLAVIX for the ordinary purpose for which consumers use it. At the time it was purchased by Plaintiff, PLAVIX was not fit for the ordinary purpose for which such drugs are used. PLAVIX was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to accomplish its purpose safely.

Defendant's breach of its implied warranty of merchantability caused Plaintiff's injuries and 1 2 monetary losses. 3 B. WARRANTY OF FITNESS 4 Defendants sold PLAVIX to Plaintiff with the knowledge that Plaintiff was 5 purchasing PLAVIX for a particular purpose. Further Defendants, knew, or should have known, 6 that Plaintiff was relying on Defendant's skill or judgment to select goods fit for Plaintiff's 7 8 purpose. Defendant delivered goods that were unfit for Plaintiff's particular purpose, and 9 123. 10 thus breached its implied warranty of fitness. Defendant's failure to select and sell a product, 11 which was reasonably safe for its intended use proximately, caused Plaintiff's injuries and 12 monetary losses. 13 THEREFORE, the Plaintiff demands judgment as to all counts in Plaintiff's favor and 14 against DEFENDANTS in a sum in excess of the jurisdictional requirement of this court; for costs 15 herein incurred; attorney's fees; for such other and further relief as this Court deems just and proper; 16 17 and demands that the issues herein contained be tried to a jury. 18 DATED this 13th day of January, 2011. 19 20 By: 21 Jeffrey B. Miller, Esq. Gabriel V. Kory, Esq. 22 MILLER WEBER KORY LLP 1112 East Washington Street 23 Phoenix, Arizona 85034 Attorney for Plaintiff 24 25 ORIGINAL of the foregoing filed with the Clerk of Court this 13th day of January, 2011. 26 27

MICHAFI K , IF A HES. CLERK 1 Jeffrey B. Miller #009771 jeff@mwkfirm.com Gabriel V. Kory, # 022536 2 11 JAN 13 PH 4: 08 gabe@mwkfirm.com MILLER WEBER KORY LLP 3 1112 East Washington Street Phoenix, Arizona 85034 4 (602) 648-4045 (602) 340-1896 (fax) Attorneys for Plaintiff 5 6 --and-P. ANN TRANTHAM, ESQ., State Bar #30972 7 1901 Texas Street Natchitoches, LA 71457 8 Telephone: (318) 352-5999 9 Email: patrantham@cp-tel.net robertsalim@cp-tel.net 10 Pro Hac to Be Submitted 11 12 13 IN SUPERIOR COURT FOR THE STATE OF ARIZONA IN AND FOR THE COUNTY OF MARICOPA 14 BEATRICE MILLS, CasCV2011-000415 15 Plaintiff, 16 ٧. 17 BRISTOL-MYERS SQUIBB COMPANY, CERTIFICATE REGARDING 18 **EXPERT TESTIMONY** SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and 19 SANOFI-SYNTHELABO, INC. 20 Defendants. 21 22 Jeffrey B. Miller, the attorney for Plaintiff herein, hereby certifies that expert opinion 23 testimony is necessary to prove the standard of care or liability with respect to Plaintiff's claims 24 against defendants, BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS, U.S., 25 L.L.C., SANOFI-AVENTIS, U.S., INC., AND SANOFI-SYNTHELABO, INC., and/or its 26 27 agents, servants and/or employees. 28

DATED this 13th day of January, 2011. By: Jeffrey B. Miller, Esq. Gabriel V. Kory, Esq. MILLER WEBER KORY LLP 1112 East Washington Street Phoenix, Arizona 85034 Attorney for Plaintiff **ORIGINAL** of the foregoing filed with the Clerk of Court this 13th day of January, 2011. 

1 2 3 4 5	Jeffrey B. Miller #009771  jeff@mwkfirm.com  Gabriel V. Kory, # 022536  gabe@mwkfirm.com  MILLER WEBER KORY LLP  1112 East Washington Street  Phoenix, Arizona 85034  (602) 648-4045 (602) 340-1896 (fax)  Attorneys for Plaintiff	FILED 11 JAN 13 PH 4:09	
6	and-		
7 8	P. ANN TRANTHAM, ESQ., State Bar #30972 1901 Texas Street Natchitoches, LA 71457 Telephone: (318) 352-5999 Email: patrantham@cp-tel.net		
10	robertsalim@cp-tel.net		
11	Pro Hac to Be Submitted		
		•	
12		STATE OF ADIZONA	
13	IN SUPERIOR COURT FOR THE IN AND FOR THE COUNTY	OF MARICOPA	
14 15	BEATRICE MILLS, Plaintiff,	CV 2011 CaGVQ.911-000415	
16			
17	V.	CERTIFICATE REGARDING COMPULSORY ARBITRATION	
18	BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S., L.L.C.,	)	
19	SANOFI-AVENTIS, U.S., INC., and SANOFI-SYNTHELABO, INC.		
20	Defendants.	) )	
21		<i>)</i> )	
22		Inlian limits and any other limitations set	
23	The undersigned certifies that he knows the c		
24	forth by the Local Rules of Practice for Maricopa County Superior Court, and further certifi		
25	that this case is not subject to compulsory arbitration,	as provided by Rules 72 through 76 of the	
26	Arizona Rules of Civil Procedure.		
27			
28			
	l .		

DATED this 13th day of January, 2011. Gabriel V. Kory, Esq. MILLER WEBER KORY LLP 1112 East Washington Street Phoenix, Arizona 85034 Attorney for Plaintiff **ORIGINAL** of the foregoing filed with the Clerk of Court this 13th day of January, 2011. 

Office Distribution

# SUPERIOR COURT OF ARIZONA MARICOPA COUNTY

\*\*FILED\*\*

4/20/2011

Clerk of the Court

4/16/2011

**COURT ADMINISTRATION** 

Ct. Admin Deputy

Case Number: CV2011-000415

**Beatrice Mills** 

V.

**Bristol-Myers Squibb Company** 

The Judge assigned to this action is the Honorable Sam J Myers

#### NOTICE OF INTENT TO DISMISS FOR LACK OF SERVICE

You are hereby notified that the complaint filed on 1/13/2011 is subject to dismissal pursuant to Rule 4 (i), Arizona Rules of Civil Procedure. The deadline for completing service is 5/13/2011. If no judge has extended time for completing service and no defendants have been served by this date, this case will be dismissed.

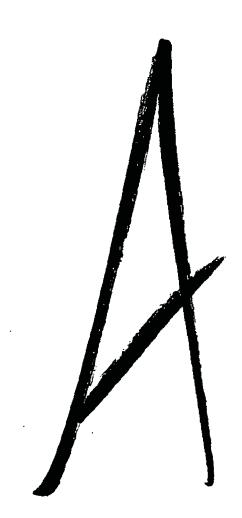
Report Version: {CV025B 1.0.2}

# Superior Court of Maricopa County - integrated Court Information System Endorsee Party Listing Case Number: CV2011-000415

Party Name	Attorney Name	 
Beatrice Mills	Gabriel V Kory	 Bar ID: 022536

		Manual management	
1	Jeffrey B. Miller #009771	MICHAEL KIJEANES, CLERK RECEIVED CCC #5 DOCUMENT DEPOSITORY	
2	jeff@mwkfirm.com Gabriel V. Kory, # 022536	11 MAY -9 PM 4: 16	
3	gabe@mwkfirm.com MILLER WEBER KORY LLP	11 mil -2 thini	
4	1112 East Washington Street Phoenix, Arizona 85034	FILED	
5	(602) 648-4045 (602) 340-1896 (fax) Attorneys for Plaintiff	By [ Men , DEP.	
6	and-		
7	P. Ann Trantham, Esq., State Bar #30972		
8	patrantham@cp-tel.net 1901 Texas Street		
9	Natchitoches, LA 71457 (318) 352-5999		
10			
11	IN SUPERIOR COURT FOR T	HE STATE OF ARIZONA	
12	IN AND FOR THE COUN	TY OF MARICOPA	
13	BEATRICE MILLS,	) Case No. CV 2011-000415	
14	Plaintiff,	) Case No. CV 2011-000413	
15	v.	MOTION AND CONSENT OF	
16	BRISTOL-MYERS SQUIBB COMPANY,	LOCAL COUNSEL FOR PRO HAC VICE ADMISSION OF	
17	SANOFI-AVENTIS U.S., L.L.C., SANOFI-AVENTIS, U.S., INC., and	PATTY ANN TRANTHAM	
18	SANOFI-SYNTHELABO, INC.	) (Assigned to the	
19	Defendants.	) Honorable Sam Myers)	
20		)	
21			
22	Jeffrey B. Miller, attorney for Plaintiff he	erein, pursuant to Rules 33 (c) and 34 (d),	
23	Rules of Supreme Court, moves this Court to admit Patty Ann Trantham as counsel pr		
24	hac vice in this action.		
25	Pursuant to Rule 34(b), Rules of the Supreme Court, the following exhibits ar		
26	attached hereto:		
27	A. the Original Verified Application i	for Patty Ann Trantham;	
28			

ı			
1	B. the Original Certificates of Good Standing for Patty Ann Trantham;		
2	C. the State Bar of Arizona Notice of Receipt for Patty Ann Trantham;		
3	The filing fees as required by Rule 34(d) have been submitted to the State Bar of		
4	Arizona. I hereby agree to serve as designated local counsel for the subject case.		
5	proposed Order admitting Patty Ann Trantham accompanies this Motion.		
6	RESPECTFULLY SUBMITTED this 9th day of May, 2011.		
7	MILLER WEBER KORY LLP		
8			
9	By January By Miller, Esq.		
10	(1112 East Washington Street Phoenix, Arizona 85034		
11	Attorneys for Plaintiff		
12	ORIGINAL of the foregoing filed with the Clerk of the Court		
13	ORIGINAL of the foregoing filed with the Clerk of the Court this 9 <sup>th</sup> day of May, 2011, with a copy for delivery to:		
14	The Honorable Sam Myers  MARICOPA COUNTY SUPERIOR COURT		
15	Central Court Building - #7 201 West Jefferson		
16	Phoenix, Arizona 85003-2243		
17	COPY of the foregoing mailed this 9 <sup>th</sup> day of May, 2011, to:		
18	P. Ann Trantham, Esq.		
19 20	1901 Texas Street Natchitoches, LA 71457		
21	Ву 760		
22			
23			
24			
25			
26			
27			
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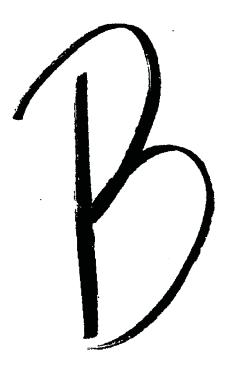


For Official Use Only 140
App# 1006/40

Attn: Pro Hac Vice Dept PO Box 53099 Phoenix, AZ 85072-3099 Phone: 602-340-7239

Application for Appearance Pro Hac Vice			
PART I: Applicant Information Name of Applicant: Patty Ann Trantham			
Firm/Company Name: Law Office of Ro	bert L. Salim		
Office Address: 3100 Richmond Ave., S	uite 480, Houston, TX 7709	98	
Telephone: 713-528-0366	Fax:	Email Address: patran	tham@gmail.com
Residence Address: 1716 Washington A	ve., Suite H, Houston, TX	77007	
Title of cause or case where applicant se		s v. Bristol-Myers Squibb et. al	
Docket Number: CV2011-000415	· · · · · · · · · · · · · · · · · · ·		
Court, Board, or Administrative Agency	: Superior Court of Arizona	, County of Maricopa	
Party on whose behalf applicant seeks to	appear: Beatrice Mills		<del></del>
		he applicant shall complete the in	
Courts to Which Applicant Has Been Ac (Attach additional pages if needed)		Date of Admission:	Bar Number:
United States Court of Appeal, Fifth Cit		December 2009	
Supreme Court of Texas		May 2009	24067910
Supreme Court of Louisana		April 2007	30972
Applicant is a member in good standing	ng in such courts.		
Applicant is not currently disbarred or	suspended in any court.		
Applicant is / is not (select one) or organization authorized to discipline a	urrently subject to any pend attorneys at law.	ing disciplinary proceeding or inve	stigation by any court, agency
In the preceding three (3) years, applicar	nt has filed applications to a	ppear as counsel under AZ ST S.Co	, Rule 38(a) in the following:
Title of Matter:	Docket #:	Court or Agency:	App Granted? (Y/N)
Villafane v. Teva Pharmaceuticals	CV-10-1099-PHX-ROS	USDC District of Arizona_	Y
			<del></del>
This case or cause is / is not (select pro hac vice in Arizona. If this matter is review and comply with appropriate rule If applicable, please provide related or concepts of the control	a related or consolidated was of procedure as required in	ith any previous application, Appli in the underlying cause.	previously applied to appear cant certifies that he/she will  2 2011
		By	- In the

Page 2		·	
PART II: Local Counsel Information Name of Arizona Local Counsel: Jeffrey B. 1	Miller		
State Bar of Arizona Number: 009771			
Address: 1112 East Washington St., Phoenix	, AZ 85034		
Telephone: 602-253-3554	Fax: 602-340-1896 Email	Address: jeff@rmgmo.com	
✓ Local Counsel is a member in good standi	ing.		
Local Counsel associating with a nonresident attorney in a particular cause shall accept joint responsibility with the nonresident attorney to the client, to opposing parties and counsel, and to court, board, or administrative agency in that particular cause.			
PART III: Parties and Certification Name(s) of each party in this cause and name	e and address of all counsel of record:	:	
Party:	Counsel of Record:	Address:	
		1112 E. Washington St, Phoenix, AZ	
Beatrice Mills	Jeffrey B. Miller	1112 E. Washington St, Filoemx, AZ	
Applicant is including with this application a nonrefundable application fee, payable to the State Bar of Arizona, in the amount of \$460.00. Fifteen percent of the non-refundable application fee paid pursuant to this section shall be deposited into a civil legal services fund to be distributed by the Arizona Foundation for Legal Services and Education entirely to approved legal services organizations, as that term is defined in subparagraph (f) of this rule.  Applicant is furnishing a certificate from the state bar or from the clerk of the highest admitting court of each state, territory, or insular possession of the United States in which the nonresident attorney has been admitted to practice law certifying the nonresident attorney's date of admission to such jurisdiction and the current status of the nonresident attorney's membership or eligibility to practice therein. The certificate furnished shall be no more than forty-five (45) days old.  Applicant certifies the following:  1. Applicant shall be subject to the jurisdiction of the courts and agencies of the State of Arizona and to the State Bar of Arizona with respect to the law of this state governing the conduct of attorneys to the same extent as an active member of the State Bar of Arizona, as provided in Rule 46(b) Rules of the Supreme Court.  2. Applicant will review and comply with appropriate rules of procedure as required in the underlying cause.  3. Applicant understands and shall comply with the standards of conduct required of members of the State Bar of Arizona.			
	Verification		
County of Natchitaches ss.  I, Nath Ann Tran Ham swear that all statements in the application are true correct and complete to the best of myknowledge and belief.  Dated: April 28; 2011 Applicant's Signature: Applicant's Signature: April 2011 by Applicant  SUBSCRIBED AND SWORN TO before me this 2844 day of April 2011 by Name of Applicant  Name of Applicant			
Revised 01/15/09	Nota	ry Public	



# United States of America

# State of Louisiana

# Supreme Court of the State of Louisiana

I, JOHN TARLTON OLIVIER, Clerk of the Supreme Court of the State of Louisiana, do hereby certify that

# PATTY ANN TRANTHAM, ESQ., #30972

was duly admitted and licensed to practice as an attorney and counselor at law in this Court and the several courts of the State of Louisiana, on the 26th Day of April, 2007 A.D.; and is currently in good standing, and sufficiently qualified to perform the duties of an attorney and counselor at law.

IN WITNESS WHEREOF, I hereunto sign my name and affix the seal of this Court, at the City of New Orleans, this the 13th Day of April, 2011, A.D.

Clerk of Court
Supreme Court of Louisiana

# The Supreme Court of Texas

**AUSTIN** 

CLERK'S OFFICE

I, BLAKE HAWTHORNE, Clerk of the Supreme Court of Texas, certify that the records of this office show that

# Patty Ann Faulkenberry Trantham

was duly admitted and licensed as an attorney and counselor at law by the Supreme Court of Texas on the 1st day of May, 2009.

I further certify that the records of this office show that, as of this date

# Patty Ann Faulkenberry Trantham

is presently enrolled with the State Bar of Texas as an active member in good standing.

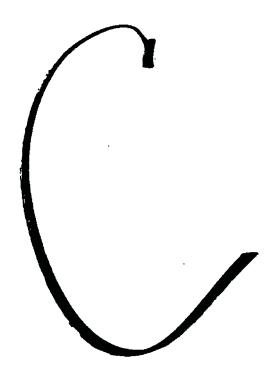
IN TESTIMONY WHEREOF witness my hand and the seal of the Supreme Court of Texas at the City of Austin, this, the 11th day of April, 2011.

BLAKE HAWTHORNE, Clerk

Brad Sonego, Deputy Clerk

by Bred Souge

No. 0411T



1	Maricopa Superior Court		
2	Plaintiff	CASE # CV2011-000415	
4	Bristol-Myers Squibb et al,	SBA App #1006140  NOTICE OF RECEIPT OF COMPLETE  APPLICATION	
6 7	NOTICE IS HEREBY given by THE STATE BAR OF A	ARIZONA that it has <u>received the verified</u>	
8	pursuant to Rule38 (a), within the previous three (3) ye	following applications to appear pro hac vice, ears:	
10	Title of Matter Court/Agency	Date Granted?	
11 12	Exhibit A, the original verified application and Exhibit I	3, the original Certificate(s) of Good Standing	
13	DATED this 6 <sup>st</sup> day of May 2011	$Q \circ O$	
14 15	_	Fac Func	
16	Re	esource Center ate Bar of Arizona	
17	7		
18	Original Manages of this end of that the		
19 20	9 Jeffrey Boyd Miller Roush McCracken Guerrero Miller & Ortega 0 1112 E Washington St		
21	Phoenix, AZ 85034-1010		
22	2		
23	3		
24	4		
25	5		